

REMARKS

The claims now pending in the application are Claims 1-6, 9-18, 21, 24-26 and 30-35. Of these claims, Claim 1 alone is in independent form with all of the remaining pending claims being dependent therefrom.

Claim 1 has been amended, *inter alia*, by replacing the transitional phrase "comprising" with "consisting essentially of", thereby limiting the scope of the claims to the specified components and those that do not materially affect the basic and novel characteristics of the osteoimplant. *In re Janakirama-Rao*, 317 F.2d 951, 137 USPQ 893 (CCPA 1963); *Ex parte Davis*, 80 USPQ 448 (Pat. Off. Bd. App. 1948).

Support for the term "covalent" in Claim 1 is found in the specification at page 14, lines 13-18.* Although the term "covalent" does not explicitly appear therein, the specification implicitly, i.e., inherently, describes covalent bonding in that functional reactive groups on the chemical crosslinking agent react with functional groups on the exposed collagen molecules of adjacent bone-derived elements to form a reinforcing cross-bridge bonding such elements to each other.

Support for the expression "formed by chemical crosslinking agent" in Claim 1 is found in the specification at page 14, line 2 to page 16, line 15 and Examples 1, 3 and 5 illustrating the use of formalin as chemical crosslinking agent.

* The cited text in the specification reads as follows:

Chemical crosslinking agents include those that contain bifunctional or multifunctional reactive groups, and which react with functional groups on amino acids such as epsilon-amine functional group of lysine or hydroxy-lysine, or the carboxyl functional groups of aspartic and glutamic acids. By reacting with multiple functional groups on the same or different collagen molecules, the reacting chemical crosslinking agent forms a reinforcing cross-bridge.

The Examiner has objected to the specification in lacking a reference to the parent application. This objection is believed to have been overcome by the amendment to page 1 of the specification.

The Examiner has rejected Claims 1-7, 9-11, 13, 14, 19-21, 23, 24, 34-43, 45, 56-61, 74-80, 82, 93-94 and 135-140 as anticipated by, or as obvious over, Lyle.

The amended claims presented herein are believed to be patentable over Lyle in several respects.

As noted above, the claims in their recitation of the transitional phrase "consisting essentially of" are limited to the recited components and any others that do not materially affect the basic and novel characteristics of the osteoimplant herein. Lyle discloses an osteoprosthetic implant possessing an osteogenic coating composition consisting essentially of demineralized bone powder, i.e., bone from which substantially all of the original mineral content has been removed, typically by treatment with a mineral acid over several hours. In contrast to demineralized bone powder, the superficially demineralized bone-derived elements present in applicants' osteoimplant have had mineral content removed only from their surfaces for the purpose of exposing surface collagen for subsequent crosslinking. Superficially demineralized bone-derived elements still retain most of their mineral content and hence their mechanical strength (specification, page 6, lines 15-18). Addition of Lyle's demineralized bone particles, a material lacking in the sort of mechanical strength associated with nondemineralized bone, to applicants' osteoimplant would only *reduce* the mechanical strength of the

osteointegration, a result which is inimical to achieving applicants' claimed characteristic compression strength.

The Examiner asserts that the Lyle demineralized bone particles are "linked together" with a binder such as cyanoacrylate. By way of emphasizing the nature of the *chemical* linking of applicants' superficially demineralized bone-derived particles to each other as distinguished from Lyle's *embedding* his demineralized bone particles in cyanoacrylate polymer, applicants have further amended Claim 1 to recite "covalent chemical linkages". Lyle's bone particles are not chemically linked, much less linked by covalent chemical linkages. This is clearly shown to be the case in Lyle's Fig. 2 in which bone particles 31 are separated from each other, and surrounded by (except at surface 30), binder 32.

The Examiner continues to assert that adhesives or binders inherently act via covalent, non-covalent bonds, hydrogen bonding, Van der Waals bonds or ionic bonds. Since the claims now specifically recite that the bonds linking the superficially demineralized bone-derived elements are covalent in nature, and since it is well-recognized in the science of chemistry that covalent bonds differ from all other types of bonds, the Examiner's assertion need only be considered in regard to the alleged inherent presence of covalent bonds in Lyle.

Applicants' previous amendment submitted evidence directly going to the Examiner's allegation of the aforesaid inherency in Lyle. The contents of the printouts of the two internet publications discussed therein ([http: www.kiss-cote.com/science/chemtxt.html](http://www.kiss-cote.com/science/chemtxt.html) and www.madsci.org/posts/archives/apr2000/955665848,

[ch.r.html](#)) make it abundantly clear that adhesives such as Lyle's cyanoacrylate work by mechanical retention of cured polymer within the pores of the substrate, not by chemical bond formation. The Examiner has casually dismissed these publications as supposedly less relevant than Huo et al. on the basis that they are directed to adhesives in general while Huo et al. is directed to a cyanoacrylate adhesive just as in Lyle. Apparently, the Examiner has failed to appreciate that the second of the two internet publications (which confirms the more general teachings of the first) expressly states that in adhesives such as epoxies and *cyanoacrylates, one never gets a chemical bond between glue and substrate*. Huo et al. disclose (specification, column 25, lines 58-60) that adhesive monomers/oligomers diffuse into the surface of the tissue substrate where they cure. This is correct and the internet publications referred to above say as much. However, in characterizing the bond of cured adhesive and tissue substrate as "covalent" in nature, Huo et al. are directly contradicted by the aforementioned internet publications which, unlike Huo et al., expressly deal with the nature of the mechanism explaining the bonding action of adhesives such as the cyanoacrylates disclosed in Lyle. Huo et al. is, scientifically speaking, half right and half wrong whereas the Examiner has presented no evidence showing that *any* of the teachings and conclusions in either of the internet publications referred to herein is erroneous or contrary to scientific fact.

In view of the foregoing, all of applicants' amended claims as presented herein are considered to be patentable over Lyle.

The Examiner has rejected Claims 12 and 15-18 as obvious over Lyle.

For the same reasons presented above, applicants maintain that the invention of the pending rejected claims herein is patentable over Lyle.

The Examiner has not explicitly continued to reject applicants' claims over Boyce et al. However, as the Examiner deems applicants' Rule 131 declaration to be ineffective to antedate Boyce et al., applicants infer that it is nevertheless the Examiner's intention to maintain the rejection over this disclosure.

The Examiner's analysis of the Rule 131 declaration and his conclusions that there is (1) a lack of due diligence during the period of January 9, 1998 to January 28, 1998 and (2) a lack of a comparison of Boyce et al. with all of the claims are believed to be in error.

To begin with, MPEP 2138.06 cited by the Examiner has to do with diligence in the context of 35 U.S.C. §102(g), e.g., interference situations where there are competing claims of prior inventorship. Interferences present policy questions not involved when antedating a reference. *In re Mulder*, 219 USPQ 189 (Fed. Cir. 1983).

Applicants do not wish to be taken to suggest that *Mulder* countenances a dispensation from the need to submit any evidence of reasonable diligence when attempting to swear behind a nonstatutory bar reference but maintains that the evidence of reasonable diligence proffered by applicants does not have to rise to the "clear and convincing" level required of a junior party attempting to establish priority over the senior party in an interference. However, even with the more exact evidentiary standard that is applicable to interferences, the facts presented in applicants' Rule 131 submission show *no gap* whatsoever in the proof of reasonable diligence.

In the period of January 9, 1998 to January 28, 1998, a draft of the application herein was in circulation among a number of individuals charged with the responsibility of reviewing it and commenting upon it. Declarant Dr. Boyce states that he requested these individuals to complete their review and provide him with their comments by January 19, 1998. Although the review and comments sought were not completed until January 28, 1998, this cannot be considered unreasonable given the corporate research setting of these tasks and the implicit understanding that January 19, 1998 was not intended to be a rigid date but the Examiner's analysis and conclusion of a lack of showing of diligence by applicants can only be premised on the view that the showing of diligence must surpass that of a reasonable diligence. This, of course, is not the law and the Examiner has thus far cited no authority that would suggest otherwise.

As for the supposed lack of a proper comparison in applicants' Rule 131 declaration, such a declaration need show only so much of the claimed invention as the Boyce et al. patent shows. *In re Stempel*, 113 USPQ 77, 81 (CCPA 1957). Since the declaration antedates Stempel with regard to its broadest claim, i.e., Claim 1, this is all that is required to effectively antedate Boyce et al.

In view of the foregoing, Boyce et al. is believed to have been antedated by applicants' Rule 131 submission and therefore no longer available as a prior art reference herein.

Reconsideration and allowance by the Examiner of Claims 1-6, 9-18, 21, 24-26
and 30-35 are respectfully requested.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Peter G. Dilworth". The signature is fluid and cursive, with a large initial "P" and "D".

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